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109TH CONGRESS
2D SESSION

H. R. 4769

To amend the Federal Food, Drug, and Cosmetic Act, the Controlled Substances Import and Export Act, and the Public Health Service Act to impose requirements respecting Internet pharmacies, to require manufacturers to implement chain-of-custody procedures, to restrict an exemption respecting the importation of controlled substances for personal use, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2006

Mr. NORWOOD (for himself and Mr. STRICKLAND) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act, the Controlled Substances Import and Export Act, and the Public Health Service Act to impose requirements respecting Internet pharmacies, to require manufacturers to implement chain-of-custody procedures, to restrict an exemption respecting the importation of controlled substances for personal use, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prescription Drug Abuse Elimination Act of 2006''.

SEC. 2. INTERNET PHARMACIES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following:

''SEC. 503B. INTERNET SALE OF PRESCRIPTION DRUGS.

''(a) IN GENERAL.—

''(1) PROHIBITIONS.—Subject to paragraph (2), it is a violation of this section—

''(A) for any person to sell a prescription drug in interstate commerce through an Internet site—

''(i) if the Internet site is an illegal Internet pharmacy under subsection (b);

''(ii) if the person fails to comply with the treating provider verification requirements of subsection (c); or

''(iii) if the person fails to submit the notices required by subsection (d); or

''(B) for any person to own or operate an illegal Internet pharmacy in interstate commerce.

''(2) EXCEPTION.—Any person who sells a prescription drug through an Internet site, or who owns

or operates an Internet pharmacy, is deemed to meet the requirements of this section for purposes of such sale, ownership, or operation if the Internet site or Internet pharmacy is certified by the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites program.

''(b) INTERNET PHARMACY REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of this section:

''(A) The term 'Internet pharmacy' means an Internet site, inside or outside the State involved, that—

''(i) is used or attempted to be used to communicate with, or obtain information from, a person for the purpose of filling or refilling a prescription; or

''(ii) is otherwise used in the practice of pharmacy, including dispensing, distributing or delivery of, or aiding in the delivery of, a prescription drug to a person.

''(B) The term 'illegal Internet pharmacy' means an Internet pharmacy that fails to comply with this subsection.

''(2) REQUIREMENTS.—An Internet pharmacy shall provide to any individual who accesses the pharmacy the following information:

''(A) The street address and telephone number of—

''(i) the Internet pharmacy's place of business; and

''(ii) the Internet pharmacy's supervising pharmacist.

''(B) All States in which the Internet pharmacy is licensed or otherwise authorized to dispense prescription drugs.

''(C) If the Internet pharmacy makes referrals to, or solicits on behalf of, a practitioner or a group of practitioners for prescription services—

''(i) the name, street address, and telephone number of such practitioner or group; and

''(ii) each State in which each practitioner involved is licensed or otherwise authorized to prescribe drugs.

''(D) A statement that the Internet pharmacy will dispense prescription drugs only upon a showing of a prescription.

''(c) TREATING PROVIDER VERIFICATION REQUIREMENTS.—The treating provider verification requirements of this subsection are as follows:

''(1) IN GENERAL.—Subject to paragraph (2), a person may sell a prescription drug in interstate commerce through an Internet site only if—

''(A) the sale is in accordance with a prescription of the treating provider of the patient involved;

''(B) the seller verifies the prescription in accordance with paragraph (3);

''(C) the seller maintains a record of direct communications in accordance with paragraph (4); and

''(D) the seller complies with the prohibition of paragraph (5) against alteration of the prescription.

''(2) LIMITATION.—The treating provider verification requirements of this subsection apply with respect to a prescription drug only if—

''(A) the prescription drug is included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act; or

''(B) the Secretary for purposes of this section identifies the prescription drug as po-

tentially subject to abuse, diversion, and misuse.

''(3) VERIFICATION REQUIREMENT.—

''(A) REQUIREMENT.—A seller verifies a prescription in accordance with this paragraph if—

''(i) the patient involved or the patient's treating provider presents the prescription, directly or by facsimile or electronic mail, to the seller; or

''(ii) the seller verifies the prescription by direct communication with the treating provider involved.

''(B) INFORMATION.—When seeking verification of a prescription under subparagraph (A)(ii), a seller shall provide to the treating provider the following information:

''(i) Patient's full name and address.

''(ii) Identification of the drug by a national drug code number.

''(iii) Quantity to be dispensed.

''(iv) Date of patient request.

''(v) Date and time of verification request.

''(vi) Name of contact person at seller's company, including facsimile and telephone number.

''(C) VERIFICATION EVENTS.—A prescription is verified under subparagraph (A)(ii) only if one of the following occurs:

''(i) The treating provider confirms the prescription is accurate by direct communication with the seller.

''(ii) The treating provider informs the seller that the prescription is inaccurate and provides the accurate prescription.

''(iii) The treating provider fails to communicate with the seller within 48 hours, or a similar time as defined by the Commissioner of Food and Drugs, after receiving from the seller the information described in subparagraph (B).

''(D) INVALID PRESCRIPTION.—If a treating provider informs a seller before the deadline under subparagraph (C)(iii) that the prescription is inaccurate or expired, the seller shall not fill the prescription. The treating provider shall specify the basis for the inaccuracy or invalidity

of the prescription. If the prescription communicated by the seller to the treating provider is inaccurate, the treating provider shall correct it.

''(4) RECORD REQUIREMENT.—A seller shall maintain for at least 2 years a record of all direct communications with a treating provider regarding the sale of a prescription drug, including verification of the prescription involved.

''(5) NO ALTERATION.—

''(A) IN GENERAL.—A seller may not alter a prescription for a prescription drug.

''(B) EXCEPTIONS.—Notwithstanding subparagraph (A)—

''(i) if the same prescription drug is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a prescription drug manufactured by that company under another label; and

''(ii) the seller may fill the prescription with a generic version of the prescription drug.

''(6) DEFINITIONS.—In this subsection:

"(A) The term 'direct communication' includes communication by telephone, facsimile, or electronic mail.

"(B) The term 'generic version of the prescription drug' means, with respect to a prescription drug, a drug for which an application is approved under section 505(j) and for which the relevant listed drug described in section 505(j)(2) is such prescription drug.

"(C) The term 'seller' means a person that sells a prescription drug in interstate commerce through an Internet site.

"(D) The term 'treating provider' means a health care provider (including a nurse) licensed by law to administer the prescription drug involved who—

"(i) has performed a documented patient evaluation of the individual involved (including a patient history and physical examination) to establish the diagnosis for which the prescription drug involved is prescribed, has discussed with the individual his or her treatment options and the risks and benefits of treatment, and maintains

contemporaneous medical records on the individual;

"(ii) is providing care in consultation with a health care provider described in clause (i) and who has access to the medical records of the patient involved; or

"(iii) is providing care as part of an on-call or cross-coverage arrangement with a health care provider described in clause (i).

"(d) STATE NOTICE REQUIREMENTS.—A person that sells a prescription drug in interstate commerce through an Internet site shall provide to each State authority that licenses or otherwise authorizes the person to dispense the prescription drug the following information:

"(1) A statement that the person is selling prescription drugs through an Internet site.

"(2) The name, Internet address, street address, and telephone number of the person's business for selling such drugs.

"(e) DEFINITION.—In this section, the term 'prescription drug' means a drug subject to section 503(b).".

(b) INCLUSION AS PROHIBITED ACT.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

331) is amended by inserting after paragraph (k) the following:

''(l) The sale of a prescription drug, or the ownership or operation of an illegal Internet pharmacy, in violation of section 503B.''.

(c) LINKS TO ILLEGAL INTERNET PHARMACY.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c) In the case of a violation of section 503B relating to an illegal Internet pharmacy, the district courts of the United States and the United States courts of the Territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, a site violating such section, or a link to a site violating such section, that resides on a computer server that such provider controls or operates. Such relief shall—

''(1) be available only after provision to the provider of notice and an opportunity to appear;

''(2) not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 503B;

''(3) specify the provider to which the relief applies; and

''(4) specifically identify the location of the site or link to be removed, or to which access is to be disabled.''.

SEC. 3. DISTRIBUTION AND LABELING OF DRUGS.

(a) DRUG PEDIGREES.—With respect to any State that imposes a requirement on the manufacturer or distributor of a drug to provide information to persons receiving the drug regarding prior sales, purchases, or trades of the drug, the Secretary of Health and Human Services shall—

(1) encourage the State to allow the manufacturer or distributor to take advantage of technological advances, including by providing such information electronically; and

(2) at the request of the State, provide technical assistance in implementing the requirement.

(b) CHAIN-OF-CUSTODY REQUIREMENTS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) (as amended by section 2) is amended—

(1) in section 502, by adding at the end the following:

''(x) If it is a drug with respect to which the manufacturer, importer, distributor, or retailer fails to comply with the chain-of-custody requirements of section 503C.''; and

(2) by inserting after section 503B (as added by section 2) the following:

"SEC. 503C. CHAIN-OF-CUSTODY REQUIREMENTS.

"(a) IN GENERAL.—Not later than January 1, 2007, the Secretary shall promulgate chain-of-custody requirements applicable to each manufacturer, importer, distributor, and retailer of a prescription drug.

"(b) MANUFACTURERS.—The chain-of-custody requirements promulgated under this section shall require each manufacturer of a prescription drug—

"(1) to incorporate a unique identifier into the packaging or labeling of the drug;

"(2) to track the drug through the point of delivery to the retailer of the drug; and

"(3) to maintain, either directly or through a contractor, a database on the movement of the drug.

"(c) IMPORTERS, DISTRIBUTORS, AND RETAILERS.—The chain-of-custody requirements promulgated under this section shall require each importer, distributor, and retailer of a prescription drug to assist in the tracking of the drug under this section by reporting the receipt of the drug to the manufacturer.

"(d) PRESCRIPTION DRUG.—In this section, the term 'prescription drug' means a drug subject to section 503(b).

''(e) EFFECTIVE DATE.—The chain-of-custody requirements promulgated by the Secretary under this section shall take effect on January 1, 2009.''.

(c) GRANTS FOR COMMUNITY PHARMACISTS.—The Secretary of Health and Human Services may make grants to community pharmacists to assist such pharmacists to comply with tracking requirements imposed on such pharmacists by drug manufacturers, importers, or distributors as a result of the amendments made by subsection (b).

SEC. 4. RESTRICTION ON PERSONAL USE EXEMPTION FOR IMPORTING CONTROLLED SUBSTANCES.

Paragraph (2) of section 1006(a) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)) is amended by striking ''may not import the controlled substance'' and all that follows and inserting: ''may not import the controlled substance into the United States—

''(1) in an amount that exceeds 50 dosage units of the controlled substance; or

''(2) in the case of a controlled substance in schedule II, III, or IV, more than 1 time during any 30-day period.''.

SEC. 5. WORKING GROUP ON PHARMACEUTICAL COUNTERFEITING.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall convene a working group (in this section referred to as the ''working group'') to conduct a study and submit a report on pharmaceutical counterfeiting.

(b) MEMBERS.—The Secretary shall invite to serve as members of the working group representatives of the following:

(1) Domestic regulatory agencies.

(2) Domestic and international law enforcement officials.

(3) Multinational organizations, such as the World Trade Organization and the World Health Organization.

(4) The United States Trade Representative.

(5) The pharmaceutical industry.

(6) Trade associations, including associations representing each step of the pharmaceutical delivery system (including representatives of drug manufacturers and pharmacists).

(c) STUDY.—The study conducted by the working group on pharmaceutical counterfeiting shall consider the following:

(1) How to enhance supply-chain security.

(2) Consumer education on counterfeiting issues.

(3) Employing technology designed to frustrate organized and sophisticated criminals intent on compromising the world's drug supply.

(4) How industry could assist law enforcement by analyzing suspected counterfeit drugs to determine authenticity.

(5) How industry can collaborate on issues related to pharmaceutical counterfeiting without revealing trade secrets or other confidential information.

(d) REPORT.—Not later than 2 years after the date of the enactment of this Act, the working group shall submit a report to the Congress on the results of the study conducted under this section, including recommendations on measures to reduce or eliminate problems associated with pharmaceutical counterfeiting.

SEC. 6. STUDY ON UNUSED CONTROLLED SUBSTANCES.

(a) STUDY.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall conduct a study to determine the best methods to

ensure that unused controlled substances are not diverted for unlawful use.

(b) CONSULTATION.—In conducting the study required by this section, the Secretary shall consult with the Administrator of the Drug Enforcement Administration, appropriate law enforcement representatives, the Administrator of the Environmental Protection Agency, States and municipalities (including State boards of pharmacy), and representatives of the pharmaceutical industry.

(c) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit a report to the Congress on the results of the study conducted under this section.

SEC. 7. BASELINE RESEARCH ON PRESCRIPTION DRUG ABUSE.

(a) RESEARCH.—The Secretary of Health and Human Services shall conduct research on issues related to prescription drug abuse, including the following:

(1) Enhancing existing public use surveys and other sources so as to provide appropriate baseline data and data on the natural history and context of prescription drug use in order to evaluate the extent and nature of potential problems and guide corrective actions which reduce the problems without unintentionally hindering patient access.

(2) The phenomenon of iatrogenic addiction, including the actual incidence and prevalence of iatrogenic addiction, the factors that modulate the risk of such addiction, and the extent to which concern about iatrogenic addiction impacts health care delivery.

(3) Development of postapproval surveillance approaches that can detect and address potential risks of abuse and misuse, including risks in diverse patient populations that did not previously appear at risk for diversion or abuse, and in geographic regions that have been relatively absent from risk.

(4) Methods to better translate new ideas about terminology, diagnosis, and management of addiction diseases into clinical practice at the primary care and specialist levels.

(5) Reliable, useful assessment tools for addiction in the clinical setting of initial and ongoing treatment of conditions requiring the use of controlled substances.

(6) Development of better methods of ensuring patient adherence to prescribed drug regimens.

(7) Relative contributions of genetic, psychosocial, environmental, and behavioral factors to addiction to prescription opioids.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the results of the research conducted under this section.

SEC. 8. DATABASE FOR DRUG ABUSE MORTALITY REPORTING.

Section 505 of the Public Health Service Act (42 U.S.C. 290aa–4) is amended—

(1) in subparagraph (B) of subsection (c)(1), by striking ", as indicated in reports by coroners"; and

(2) by adding at the end the following:

"(e) With respect to the activities of the Administrator under subsections (a) and (c)(1)(B) relating to the collection of data on the number of deaths occurring as a result of substance abuse, the Administrator—

"(1) shall expand and intensify collection activities to maintain a comprehensive, national database on such deaths; and

"(2) shall require medical examiners, coroners, and other appropriate persons to report to the Administrator for purposes of collecting data on such deaths.".

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